Norfolk Medical

7350 N. Ridgeway, Skokie, IL 60076 • 847-674-7075

K102385

JAN 14 2011

Section 5

510(k) Summary

Single Lumen Titanium Implanted Port

510 (k) Summary of Safety and Effectiveness Information 21 CFR 807.92

Part I
General Information

5.1 Submitter/Sponsor Information

Submitter Name:	Norfolk Medical Products, Inc.
FDA Establishment Registration Number:	1450392
Address:	7350 N. Ridgeway Skokie, IL 60076
Telephone Number:	(847) 674-7075
Fax Number:	(847) 674-7066
Contact Person:	Michael J. Dalton/President
Date of Preparation:	August 20, 2010

5.2 Device Name

Device Name:	Implanted Drug Delivery Device (Port)
Trade Name:	NorPort Family of Ports
Device Common or Usual Name:	Implantable Infusion Ports
Classification Name:	LJT- Port & Catheter, Implanted, Subcutaneous, Intravascular 21 CFR 880.5965- Subcutaneous, Implanted, Intravascular Infusion Port and Catheter, Class II

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5.3 Predicate Device Name

Device Name:	PHS Medical GmbH C-Port
Premarket Notification:	510 (k)# 091099, 2009
Device Name:	Bard Power Port Titanium Port w/8Fr
Premarket Notification:	510 (k)# 060812, 2006
Device Name:	Angiodynamycs Vortex®
Premarket Notification:	510 (k)# 081472, 2008
Device Name:	Vascular Medical Access Port, NorPort™
Premarket Notification:	510 (k)# 830000, 1983
Device Name:	Norfolk Medical, material Titanium
Premarket Notification:	510 (k)# 871192, 1987
Device Name:	Norfolk Medical, change to silicone catheter.
Premarket Notification:	510 (k)# 871209, 1987
Device Name:	Norfolk Medical, change to silicone septum.
Premarket Notification:	510 (k)# 863723, 1986
Device Name:	Norfolk Medical, material polysulfone.
Premarket Notification:	510 (k)# 840788, 1984

5.4 Device Description

Our device is composed of a port reservoir with an attachable catheter system. The Port reservoir consists of a titanium (510 (k)# 871192) or polysulfone (510 (k)# 840788) chamber with a silicone septum and an outlet section. The silicone septum is designed to allow multiple needle puncturing while maintaining the leak-tight integrity. The port comes in two different sizes to accommodate different body frames. The catheter that is attached to the port is long enough to be inserted in the superior vena cava/right atrium junction to allow for fluid infusion into the heart and large blood vessels.

The NorPort will also be available as part of an implantable kit. The kit contains all the tools needed to aid in catheter placement, insertion and port implantation.

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5.5 Indications for Use Statement and Product Function

The NorPort, (Family of Implanted Vascular Access Devices), is a subcutaneously implanted device designed for use when repeated access to the vascular system is the therapy of choice. This device provides the user with an easily located needle insertion point for use whenever introducing fluids or medications into the vascular system or for acquiring periodic blood samples.

The NorPort implantable access device is indicated for use when the patient requires the following: repeated access to the vascular system for injections, infusion drugs, administration of blood or blood products, and/or withdrawal of blood as part of the therapy regimen. Additionally, The NorPort is indicated for

use when therapy requires long-term infusion of liquids via an external infusion pump.

5.6 Contraindications or Cautions for Use

A detailed list of possible implantation complications and contraindications of the NorPort family of ports are listed in the "User's Manual" which is supplied with each NorPort Kit. Some of the possible complications due to the implantation of the Norport include, but are not limited to, infection, occlusion, embolization, catheter fragmentation, erosion, extrusion of the device, hematomas, clot formation and thrombosis.

Improper placement of the catheter in the body has been shown to cause the catheter to be cut off from a, "pinching" effect by the clavicle and the first rib. Exercise caution when placing the catheter into the vein and the superior vena cava to ensure that the catheter does not pass between the juncture of the clavicle and the first rib. This "Pinch-off" complication is well documented and a well understood potential complication of the surgical implantation of the Port system.

5.7 Methods of Application

The method of application is to prepare and insert the catheter into the vein (using "cut down" method or "percutaneous" method) and on into the junction of the superior vena cava and the right atrium. Then the proximal end of the catheter is tunneled subcutaneously to an area of cut down where the port is to be placed beneath the skin and secured to the muscle tissue. The catheter is joined to the port and the port is sutured to the muscle. All incisions are sutured normally by the physician.

Intravenous fluids, medications, blood products, or nutritional fluids may then be administered by needle puncture of the septum in the port or periodic blood samples may be acquired if appropriate flushing techniques are followed. A complete description of the uses of the port is contained in the Instructions for Use/User's Manual in Appendix B.

5.8 Special Precautions for Disposal

Any sharp instrument used in the procedure should be properly disposed of according to the institution policy. Any remaining parts or empty packages do not require special handling when disposing.

5.9 Sterilization Information

The NorPort is provided sterile and is recommended for single use only. In the event that the product becomes contaminated (not by bodily fluids or tissue) prior to use, replace it with sterile product and return the device to Norfolk Medical for repackaging and re-sterilization.

5.10 Validity Period

As long as the package remains unopened and undamaged the product is valid for use. The materials included with the NorPort kit and the NorPort do not degrade over time.

5.11 Special Precautions for Handling and Storage

Product should be stored in a cool and dry place. It should only be open prior to use.

5.12 Description of Package (NorPort Kit)

The NorPort Kit includes a port and catheter and the following inside the sterile package:

- 1 Huber Point Needle (straight needle)
- 1-Vein Pick (retraction/introduction device)
- 1- Tunneling trocar (atraumatic tip)
- 1- Blunt needle
- 1-10 mL syringe
- 1- Locking Mechanism
- 1- Patient chart Sticker
- 1- User's Manual

The plastic tray is contained within a heat-sealed polyethylene/nylon Tyvek® header bag (pouch) and sterilized. If requested a percutaneous introducer kit is included in the NorPort kit package. This Port/Introducer Kit is listed with its own catalog number. This kit might be ordered separate or as part of the kit as requested by the physician.

The percutaneous introducer kit, or "Full-Kit" as described in the brochure and catalog, contains the following:

- 1- Basic set
- 1- "Split Sheath" percutaneous introducer
- 1- J-Flex guide wire with thumb advancer
- 1- Introducer needle

In addition, the NorPort "Full-Kit" is packaged with a "User's Manual" and "Patient Implant" stickers.

Each Kit is packaged in an external fiberboard box. Each box is labeled accordingly to match the item inside the box.

5.13 Labeling

All products are properly labeled on its plastic container with a stick on label containing the following information. Refer to appendix C for sample labels.

- Company Name, Address and Contact Number
- Product Name (Brand Name and Common Name
- Catalog Number
- Catheter Size
- Lot Number
- Units included
- Restricted Device Note: Federal Law restricts this device to sale by or on the order of a physician
- Sterile unopened undamaged package
- For single use only statement

5.14 Instruction for Use

Note: Detailed instructions for use and care of the NorPort are in the "USER'S MANUAL. A simple listing of implant instruction is listed here:

1) Before implanting inspect the port thoroughly. Do not use if holes, cracks, or surface contaminations are present.

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2) Flush all air from the port prior to placement using the 20ga Huber point needle and syringe with heparinized saline, which is provided with the kit.

3) The selected site for the reservoir body should be over a bony structure and in a location that is convenient and comfortable for the patient.

4) Place the catheter into the vein using the "cut-down" technique or by using a percutaneous introducer.

5) Place the tip of the catheter in an area of high blood flow when placing it in the venous system. Fluoroscopy is highly recommended to verify proper placement of the catheter tip in the junction of the superior vena cava/high right atrium.

6) Take special care not to serrate the catheter tip or occlude it during the catheter placement process. Leave sufficient slack upon placement so the patient movement does no stress the catheter.

7) Position the pocket for the reservoir so that the suture line is not directly over the port. Do not place the port too deep or to shallow. A depth of approximately 5mm under the skin surface is recommended as the optimal placement of depth.

8) Cut the catheter to the proper length and moisten all components with saline.

9) Slide the catheter lock over the catheter.

10) Slide the catheter over the barbed outlet tube (pin connector) of the reservoir.

11) Slide the catheter lock and catheter forward until the catheter and the outlet tube are completely covered.

12) Test the connection by gently tugging on the catheter.

13) Secure the port to the underlying fascia with at least three non-absorbable sutures.

14) After suturing has been satisfactorily completed, flush the incision with an appropriate antibiotic to ensure a sterile pocket.

15) Before closure, check patency and flow through the NorPort by x-ray, fluoroscopy, or by imaging technique of choice.

16) After each use, always leave the NorPort filled with a heparinized saline solution in a concentration recommended by your institution.

A copy of the Instructions for Use/User's Manual is attached in Appendix B, which contains detailed instructions.

5.14 Technological Characteristics Summary

The following Summary Information refers to the Norfolk Medical NorPort and catheter.

Is the new device compared to Marketed Device?

- Yes, the Norfolk Medical NorPort and catheter are compared to legally marketed predicate devices.

Does the new device have the same indications for use statement?

- Yes, the Norfolk Medical NorPort and catheter have the same indications for use statement to legally marketed predicate devices.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. in deciding, impact on safety and effectiveness may be considered)?

- No, the differences do not alter the intended use of the port.

Does the new device have the same technological characteristics, e.g. design, materials, etc?

- No, not in all regards.

The NorPort implanted Port has some minor differences from the predicate devices, however, the fundamental scientific technology of the port/catheter has not changed.

Could the new characteristics affect safety and effectiveness?

- No, there are no new significant characteristics that would affect safety and effectiveness in the new device.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes,

FDA, Guidance on 510(k) Submissions for Implanted Infusion Ports, dated October 1990 was used to as a reference for the performance testing.
BS EN ISO 10555-1:2009, Sterile, single-use intravascular catheters Part 1:General requirements, was used as a testing reference.

ISO 11135-1:2007, Sterilization of health care products -Ethylene oxide- Part 1, Requirements for development, validation and routine control of a sterilization process for medical devices. Specifies requirements for the development, validation and routine control of an ethylene oxide sterilization process for medical devices.

Are performance data available to assess effects of new characteristics?

Yes, verification testing was performed according to protocols based on the above referenced guidance document recommendation and additional standards.

Do performance data demonstrate equivalence?

Yes, performance data gathered in the design verification testing demonstrated that the NorPort family of products is substantially equivalent to the predicate devices mentioned in this submission.

5.15 Non-Clinical Data

The data collected from the non-clinical tests demonstrated that the functionality and performance characteristics of the NorPort vascular port are comparable to the currently marketed vascular ports. The test performed include: catheter to port connection, septum puncture/port leak, patency verification, static burst, and tensile strength.

5.16 Conclusion

The NorPort family of products meets all established acceptance criteria for performance testing and design verification testing. Based on the FDA's decision tree, the NorPort and its components is substantially equivalent to their respective

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predicates: Norfolk Medical Vascular Access Port (K830000), the PHS C-Port (K091099), the Angiodynamics Vortex VX Port Implantable Infusion Port (K081472), and the Bard PowerPort Implanted Titanium Port Chronoflex with 8 Fr. Catheter (K060812).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Michael J. Dalton
President
Norfolk Medical Products, Incorporated
7350 N. Ridgeway
Skokie, Illinois 60076

JAN 14 2011

Re: K102385
Trade/Device Name: NorPort (Family of Implanted Vascular Access Devices) Port and Catheter, Implanted, Subcutaneous, Intravascular-LJT
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: January 5, 2011
Received: January 6, 2011

Dear Mr. Dalton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~N/A~~ K102385

Device Name:

NorPort (Family of Implanted Vascular Access Devices) Port and Catheter, Implanted, Subcutaneous, Intravascular-LJT

Indications for Use:

The NorPort Family of Implanted Vascular Access Devices is indicated for use when the patient requires repeated access to the vascular system for injections, infusion drugs, administration of blood or blood products, and/or withdrawal of blood as part of the therapy regimen.

Prescription Use __X_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 1/12/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102385